

JUL 10 2006

*Application No. 10/658718*  
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*Amendment*  
*Attorney Docket No. S63.2B-11232-US01*

**Remarks**

This Amendment is in response to the Office Action dated May 12, 2006. Claims 1-16, 18-25 and 38, drawn to a non-elected invention, have been canceled without prejudice. Applicant reserves the right to prosecute these claims in a divisional or continuation application.

**Claim Rejections**

**35 U.S.C. §112, first paragraph**

Claims 17, 26-37 and 39-43 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Office Action asserts that the claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action asserts that:

There is no basis in the original disclosure for a coating of a single polyurethane based on polytetramethylene ether glycol. There is basis for using TECOGEL 500 and 2000 alone. TECOGEL is based on polyethylene glycol (see Venkatraman col 8 line 15) not polytetramethylene ether glycol. There is basis for using a combination of TECOGEL with TECOPHILIC. There is not basis for using TECOPHILIC alone.

See page 2 of the Final Office Action mailed 5/12/2006.

This is incorrect.

First, TECOGEL® is a member of the TECOPHILIC® family. See page 2 (highlighted portion) of the enclosed brochure entitled Technical Information. These polymers comprise polytetramethylene ether glycol. As reported by the company who currently manufactures these polyurethanes, NOVEON, formerly Thermedics Polymer Products, ALL of the polyurethane formulations, with the exception of CARBOTHANES, comprise polytetramethylene glycol. See page 3, The Materials of Choice, second paragraph of the Noveon brochure entitled Noveon, The Specialty Chemicals Innovator. NOVEON purchased Thermedics Polymer Products in October of 2003. All of this information is available from their website, [www.noveon.com](http://www.noveon.com), copyright 2001- 2006 Noveon, Inc. See specifically [http://www.estane.com/Brochures/Medical\\_Intro.pdf](http://www.estane.com/Brochures/Medical_Intro.pdf).

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<http://www.estane.com/relatedProducts/ThermedicsOverview.asp>; and  
<http://www.estane.com/technology/Medical.asp#TPUFamily>.

The Office Action further asserts that "...the documentation supplied by applicant to show the identity of TECOPHILIC is undated. The identification of a trademark material must be known at the time of filing applicant's application (MPEP 608.01(v))."

Applicants are enclosing herewith, a brochure obtained from the internet archives dated 2002, which states that Tecogel is a member of the Tecophilic family of polyurethanes. Further, as admitted in the Office Action, these polymers comprise polytetramethylene ether glycol. See page 4, second paragraph of the Office Action. Applicants have therefore complied with 35 U.S.C. 112, first paragraph, as well as with MPEP 608.01(v). No new matter has been added to the claims.

It was further asserted in the Office Action that "[e]ven if the specification inherently supported the amended claims, the specification would be objected to as failing to provide proper antecedent basis for the claimed subject matter."

Applicants have amended the specification accordingly. No new matter has been added. Applicants have provided evidence showing that TECOGEL® 500 and TECOGEL® 2000, given as examples of polyurethanes which may be employed in Applicants invention (page 2, lines 23-27), are members of the TECOPHILIC® family of thermoplastic aliphatic polyether polyurethanes which comprise polytetramethylene ether glycol as admitted by the Examiner. TECOGEL® 500 and 2000 were members of this family prior to Applicants' invention. Applicants have supplied an archived internet website from 2002 in support of this.

Claims 36 and 37 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that "[c]laim 36's monoacrylates and triacrylates are not the diacrylates required by claim 35. Applicant has amended claim 35 to properly depend from claim 34. No new matter has been amended.

The Office Action asserts that "[t]here is no antecedent basis for "crosslinkable" in claim 37. Claim 37 has been amended to depend from claim 34 and the reference to "crosslinkable material" has been deleted and replaced with "diacrylate". No new matter has been added.

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Based on the foregoing arguments and amendments, Applicants respectfully request withdrawal of the rejection of claims 17, 26-37 and 39-43 under 35 U.S.C. 112, first and second paragraphs.

*35 U.S.C. 102(b)/35 U.S.C. 103(a)*

**Krishnan, 2002/0065373**

Claims 17, 26-28, 30-34, 36, 39 and 40 have been rejected under 35 U.S.C. 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krishnan, 2002/0065373.

The Office Action asserts that "Krishnan produces mixtures of polyurethane with crosslinker (abstract)....Krishnan does not specify the type of polyether segment, but the Pellethane family of urethanes used in Krishnan's example is known to be based on polytetramethylene oxide (see Borgersen 2001/0018607 paragraph 61)."

Applicants submit that Krishnan discloses *radiation cross-linked* thermoplastic polyurethane elastomer articles. See Technical Field of the Invention, abstract and paragraph 16 of the specification.

Applicants have amended independent claim 17 to clarify that the thermoplastic polyurethane employed therein, forms an interpenetrating or semi-interpenetrating polymer network. Support is found at least from page 3, lines 13-16. No new matter has been added. In such an embodiment, the crosslinker does not react with the polyurethane.

Krishnan discloses crosslinking of the thermoplastic polyurethane disclosed therein, and fails to disclose an interpenetrating or semi-interpenetrating polymer network and therefore neither anticipates nor suggests claim 17 as amended.

Independent claim 26 is directed to an embodiment wherein the polyurethane is capable of absorbing between 500% and 2000% of its own weight in water and comprises the residue of polytetramethylene ether glycol.

In order to render claim 26 unpatentable under 35 U.S.C. §102(b) or 35 U.S.C. §103(a), Krishnan et al. must either disclose or suggest polymers which have both of these most important features. Krishnan does not.

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There is no suggestion by Krishnan that the Pellethane polymer suggested for use therein is capable of absorbing any water, much less such high quantities of water absorption of between 500% and 2000% of its own weight in water as the polymer recited in claim 26, prior to crosslinking, much less after crosslinking of the polymer disclosed therein. Consequently, independent claim 26 is neither anticipated by, nor obvious over Krishnan.

Independent claim 27 is directed to an embodiment wherein the thermoplastic polyurethane is not crosslinked. Claim 27 was amended for purposes of clarity only. No new matter has been added.

Because Krishnan discloses polymers which are crosslinked, and does not suggest embodiments where the polymer is not crosslinked, claim 27 is neither anticipated by, nor obvious over Krishnan.

Claims 28, 30-34, 36, 39 and 40 depend from claim 27 and are patentable over Krishnan for at least the reasons that claim 27 is patentable over Krishnan.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 17, 26-28, 30-34, 36, 39 and 40 under 35 U.S.C. 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krishnan, 2002/0065373.

**Zamore, 2004/0002729**

Claims 17, 26-28, 30-37 and 39-43 have been rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zamore, 2004/002729.

The Office Action asserts that:

Zamore irradiates thermoplastic polymers in the presence of crosslinking monomers (abstract). The polymer can be Tecophilic (paragraph 74) which is applicant's polytetramethylene ether glycol based polyurethane. The crosslinker can be neopentylglycoldiacrylate (paragraph 69). This composition is used to coat medical articles (paragraph 55).

Office Action, page 4, second paragraph.

Applicants disagree.

Applicants submit that Zamore discloses a radiation cross-linkable medical angioplasty balloon or radiation cross-linkable medical catheter *made from* a thermoplastic

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cross-linkable composition comprising a thermoplastic polymer which is the reaction product of an aromatic polyisocyanate and a polyol and a monomer crosslinker selected from the group consisting of methacrylate monomer crosslinkers and acrylate monomer crosslinkers, for conversion of at least a portion of the thermoplastic polymer from a thermoplastic to a thermoset state upon irradiation of the composition with energy from a radiation source. See claim 1.

Applicants independent claims 17, 26 and 27, in contrast, are directed to a medical device having a lubricious *coating* including a thermoplastic polyurethane of the type recited therein, and at least one ethylenically unsaturated monomer, oligomer or prepolymer.

Therefore the embodiments recited in independent claims 17, 26 and 27 are not the same as and cannot be anticipated by Zamore under 35 U.S.C. 102(e) for at least this reason. Claims 28, 30-37 and 39-43 depend from claim 27 and are not anticipated by Zamore for at least the reasons that claim 27 is not anticipated by Zamore.

Zamore also fails to suggest that the compositions recited therein be employed as coatings, and fails to suggest that such compositions may be applied to the surface of a medical device for purposes of providing lubricity to the surface of a medical device.

Additionally, with respect to claim 17 as amended, Zamore fails to disclose or suggest an interpenetrating polymer network of the thermoplastic polyurethane and a crosslinker as recited in independent claim 17.

Additionally, with respect to claim 26, Zamore fails to disclose or suggest polymers which absorb water in amounts of 500% to 2000% of their own weight as recited in claim 26. Tecophilic polymers, as disclosed by Zamore, absorb water in the range of 150% of their own weight prior to crosslinking. See page 2 of the attached brochure. Zamore discloses thermoset or crosslinked polymers. Therefore, the embodiment recited in claim 26 is neither disclosed nor suggested by Zamore.

Additionally with respect to claim 27, Zamore fails to disclose a thermoplastic polymer employed in combination with a crosslinker which is not crosslinked as recited in claim 27. Therefore, Zamore fails to disclose or suggest the embodiment recited in claim 27.

For at least these additional reasons, claims 17, 26 and 27 are patentable over Zamore. Claims 28, 30-37 and 39-43 depend from claim 27 and are patentable for at least the reasons that claim 27 is patentable over Zamore.

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Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 17, 26-28, 30-37 and 39-43 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zamore, 2004/002729.

### CONCLUSION

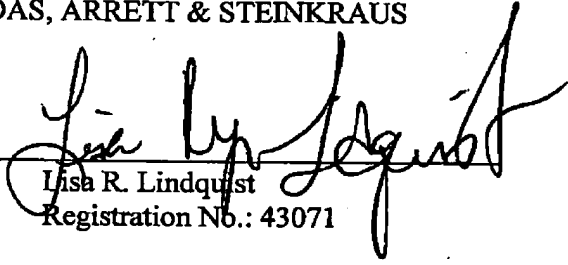
Claims 17, 26-37 and 39-43 are pending in the application. Claims 1-16, 18-25 and 38 have been canceled without prejudice. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

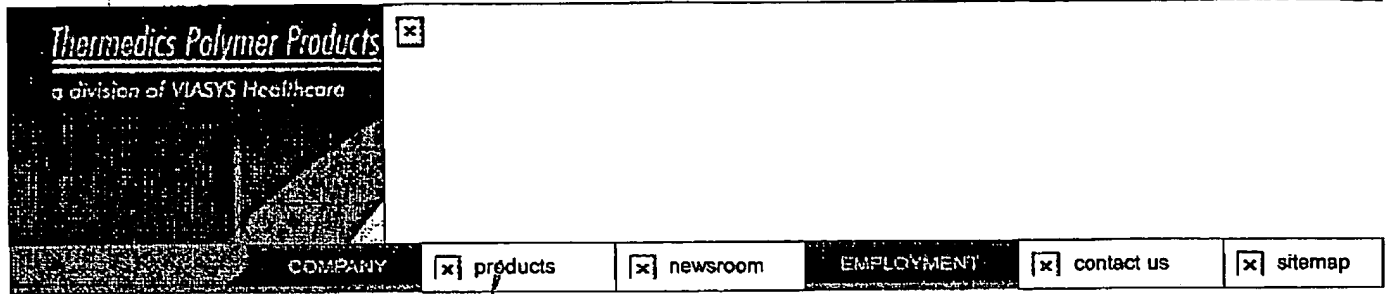
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## Medical Urethanes > The TPU Product Family

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- > Custom Extruded Urethane Tubing

### The TPU Product Family

Each of our families of resins has unique characteristics that must be considered when selecting a material for your application. The following summaries will guide you in the selection of proper material for your specific needs.

For information on these or any other product please contact Mike Voltero at 781-938-3311, Click here for online form, or browse our medical library.

#### Tecoflex®

A family of aliphatic, polyether-based TPU's available over a wide range of durometers, colors, and radiopacifiers. These resins are easy to process and do not yellow upon aging. Solution-grade versions are candidates to replace latex. Caution must be observed in evaluating these resins, especially the low durometer grades, in long-term implant applications because of potential for stress cracking.

#### Tecothane®

A family of aromatic, polyether-based TPU's available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane resins to exhibit improved solvent resistance and biostability when compared with Tecoflex resins of equal durometer. As with any aromatic polyurethane, Tecothane resins tend to yellow upon aging or when subjected to radiation sterilization.

#### Carbothane®

A family of aliphatic, polycarbonate based TPU's available over a wide range of durometers, colors, and radiopacifiers. This type of TPU is reported to exhibit excellent hydrolytic stability, a property which may equate to excellent long-term biostability.

#### Tecophilic®

A family of aliphatic, polyether-based TPU's which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution-grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating.

applications. Tecogel, a new member of the Tecophilic family, is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin.

#### Tecoplast ®



A family of aromatic, polyether based TPU's formulated to produce rugged injection-molded components exhibiting high durometers and heat deflection temperatures. Tecoplast is intended for use as hubs and fittings manufactured as individual components or insert molded onto tubing. Available as clear pellets as well as in transparent and opaque colors.

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## Technology

### Medical Urethanes

#### Solution Grade Polymers

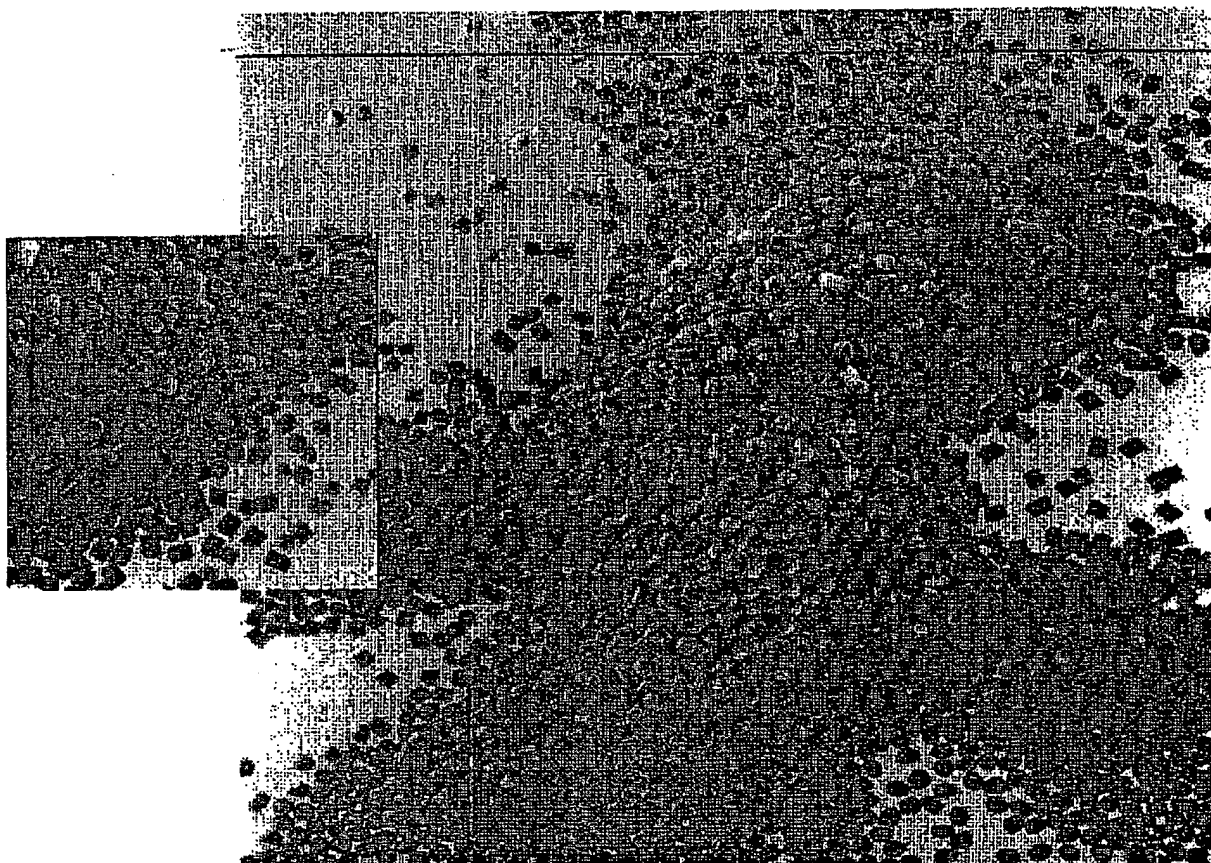
Although all Noveon polymers for medical applications can be dissolved in certain solvents, certain grades have been developed specifically for use in solution casting or for coating of medical products. The solution grades differ from the extrusion grades in that they contain no melt processing lubricants.

Tecoflex® solution grade polyurethanes are available in four hardnesses; Tecophilic® TPUs have three grade products.

Solution Processible Grades	
Tecoflex® Aliphatic TPUs	Tecophilic® Aliphatic TPUs
SG-80A	SP-80A-150
SG-85A	SP-93A-100
SG-93A	SP-60D-60
SG-60D	
Note: Last two or three characters of the Tecophilic® TPU product represent the approximate equilibrium water content.	

*Noveon disclaims any warranty of its products (Tecoflex®, Tecothane®, Carbothane®, Tecophilic® and Tecogel® TPUs) for merchantability or fitness for any particular application. The user must independently determine the suitability of these resins for such applications. Each user is responsible for obtaining all necessary FDA and other approvals for the use of these resins in their application and for complying with all applicable laws relating to the manufacture and sale of medical devices.*

# Technical Information



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The Specialty Chemicals Innovator™

[www.estane.com](http://www.estane.com)

03/04

# The Versatility of Polyurethane

The proper selection of a material in the development of a medical device is critical for the device engineer and the design team involved. Noveon offers that team a family of thermoplastic polyurethanes that have been specially formulated and manufactured for medical applications.

Noveon's polyurethanes are available in a wide range of durometers, from 72 Shore A to 84 Shore D, making them useful for a large variety of medical devices and components. Noveon's thermoplastic polyurethanes (TPUs) exhibit excellent abrasion resistance and flexural endurance as compared to other polymers of similar durometers.

The ease of processing and high strength of polyurethanes makes them the material of choice for soft elastomer applications. Silicone, for example, another common polymer used in low durometer applications, is difficult to extrude and does not bond easily to other components made of non-silicone materials. Because of the much greater strength of polyurethanes as compared to silicone, the walls of polyurethane tubing can be made much thinner, allowing for either a smaller overall diameter or a larger inside diameter for increased flow — both great benefits for indwelling device applications.

Polyurethanes eliminate the problems associated with other materials used in mid-durometer applications such as PVC, where the dangers of leachable plasticizers become a concern. TPUs also retain their elastomeric characteristics even at low temperatures where PVC becomes brittle.

Noveon's urethanes compare favorably to harder grade polymers like the fluorinated hydrocarbons. Fluorocarbons are very difficult to bond to other materials and have poor kink resistance. Again, the bondability, strength and processability of our polyurethanes make them a better choice for harder durometer applications.

Most of Noveon's polyurethanes can be loaded with radiopaque materials for detection on X-ray or fluoroscope and colored for product identification. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixture and superior smoothness of the final polymer. All additives to our polyurethanes are thoroughly screened and carefully tested for chemical stability, biocompatibility and performance in our products before use as a radiopaque or coloring agent.

The many requirements necessary for safe, practical use of an elastomer in medical devices quickly narrows the field of suitable materials. Noveon's polyurethanes pass the tests of biocompatibility, processability and chemical stability for medical device use. Wide durometer range and smooth radiopaque surfaces enhance Noveon's standing as the optimal supplier of polyurethane materials for medical device components.

Noveon's polymers are being used in numerous medical devices from pacemakers, various access devices, PEG tubes and balloons.



# The TPU Product Family

Each of our families of resins has unique characteristics that must be considered when selecting a material for your application. The following summaries will guide you in the selection of the proper material for your specific needs.

## Tecoflex® TPU

A family of aliphatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. These resins are easy to process and do not yellow upon aging. Solution grade versions are candidates to replace latex. Caution must be observed in evaluating these resins, especially the low durometer grades, in long-term implant applications because of the potential for stress cracking.

## Tecothane® TPU

A family of aromatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane® resins to exhibit improved solvent resistance and biostability when compared with Tecoflex® resins of equal durometers. As with any aromatic polyurethane, Tecothane® resins tend to yellow upon aging or when subjected to radiation sterilization.

## Carbothane® TPU

A family of aliphatic, polycarbonate-based TPUs available over a wide range of durometers, colors, and radiopacifiers. This type of TPU has been reported to exhibit excellent oxidative stability, a property which may equate to excellent long-term biostability. This family, like Tecoflex® TPUs, are easy to process and do not yellow upon aging.

## Tecophilic® TPU

A family of aliphatic, polyether-based TPUs which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating applications. Tecogel® TPU, a new member to the Tecophilic® TPU family, is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin. The materials were designed as a coating cast from an ethanol/water solvent system. Other solvent systems such as THF/water and DMAC can be used. Tecogel® TPU is melt processible using modified injection molding and extrusion methods.

## Tecoplast® TPU

A family of aromatic, polyether-based TPUs formulated to produce rugged injection molded components exhibiting high durometers and heat deflection temperatures. Tecoplast® TPU is intended for use as hubs and fittings manufactured as individual components or insert molded onto tubing. Available as clear as well as transparent and opaque colors.



Our 30,000 square foot warehouse allows us to ship standard products from stock typically within 24 hours of receipt of your order.

## Summary of Differences

<b>Property</b>	<b>Tecothane® TPU</b>	<b>Tecoflex® TPU</b>	<b>Carbothane® TPU</b>	<b>Tecophillic® TPU</b>
Yellowing	Significant concern especially for aesthetic appearance of clear components.	Minor concern	Minor concern	Minor concern
Solvent resistance	Excellent	Low durometers may exhibit considerable swelling and tackiness upon prolonged exposure to polar organic solvents	Similar to Tecoflex® TPU	Similar to Tecoflex® TPU
Softening at body temperature	Yes	Yes, to an even greater degree	Yes	Yes
Formation of MDA (Methylene Dianiline)	Possible if resin or product is improperly processed	Not possible	Not possible	Not possible
Melt processing Temperatures	High temperatures 195°C to 230°C 380°F to 450°F	Lower temperatures 155°C to 190°C 310°F to 375°F	High temperatures 185°C to 215°C 365°F to 420°F	Lower temperatures 155°C to 190°C 310°F to 375°F

# Tecoflex® TPU Typical Physical Test Data

## CLEAR GRADES

ASTM Test	EG-80A	EG-85A	EG-93A	EG-100A	EG-80D	EG-65D	EG-68D	EG-72D
D2240 (Shore D Hardness)	72A	73A	73A	74A	75A	76D	75D	77D
Specific Gravity	D792	1.04	1.05	1.08	1.09	1.09	1.10	1.11
Flexural Modulus (psi)	D790	1,000	2,300	3,200	6,000	13,000	17,000	22,000
Ultimate Tensile (psi)	D412	5,800	6,200	7,700	8,200	8,300	8,300	8,100
Ultimate Elongation (%)	D412	600	500	360	320	280	300	310
Tensile (psi)	D412							
at 100% Elongation		300	600	1,000	1,600	1,800	2,200	3,400
at 200% Elongation		500	900	1,900	3,000	2,900	3,000	4,800
at 300% Elongation		800	1,400	4,300	5,600	5,600	6,000	7,100
Heat Deflection Temp (ASTM D1525) (°C)	D1525	105	110	110	110	110	115	115
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.005-.010	.004-.008	.004-.008	.004-.006

## RADIOPAQUE GRADES (20% loading of barium sulfate)

ASTM Test	EG-80A-B20	EG-85A-B20	EG-93A-B20	EG-100A-B20	EG-60D-B20	EG-65D-B20	EG-68D-B20	EG-72D-B20
D2240 (Shore D Hardness)	72A	73A	73A	74A	75A	76D	75D	77D
Specific Gravity	D792	1.24	1.25	1.27	1.29	1.32	1.32	1.31
Flexural Modulus (psi)	D790	1,200	2,700	3,900	7,000	12,000	16,000	25,000
Ultimate Tensile (psi)	D412	5,100	5,600	6,900	7,100	7,500	7,000	6,500
Ultimate Elongation (%)	D412	700	600	360	370	310	320	310
Tensile (psi)	D412							
at 100% Elongation		400	700	1,000	1,700	2,000	2,900	3,600
at 200% Elongation		600	1,100	1,800	2,600	3,100	3,600	4,200
at 300% Elongation		900	1,600	3,100	4,900	5,600	6,000	NA
Heat Deflection Temp (ASTM D1525) (°C)	D1525	105	110	110	110	110	115	115
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.008	.004-.008	.004-.006

This test data represents the most recent additions and updates to the Tecoflex® TPU family of aliphatic polyether-based polyurethane and should be referenced accordingly. These NOTE: test results are based on small samples of Tecoflex® TPU polyurethane and do not necessarily represent average results from larger test samples. This information should not be used for establishing engineering or manufacturing guidelines.

# RADIOPAQUE GRADES (40% loading of barium sulfate)

		EG-80A-B40	EG-85A-B40	EG-93A-B40	EG-100A-B40	EG-60D-B40	EG-65D-B40	EG-72D-B40
ASTM Test								
Barium Sulfate Content (%)	D2240	80	85	93	100	60	65	72
Specific Gravity	D792	1.48	1.50	1.52	1.53	1.53	1.54	1.55
Flexural Modulus (psi)	D790	1,500	1,700	1,700	1,700	2,700	3,000	3,000
Ultimate Tensile (psi)	D412	4,700	4,900	6,500	6,600	6,800	6,200	5,700
Ultimate Elongation (%)	D412	650	550	480	420	370	330	390
Tensile (psi)	D412							
at 100% Elongation		500	900	1,400	2,100	2,200	3,000	4,300
at 200% Elongation		900	1,400	2,000	2,700	2,900	3,500	NA
at 300% Elongation		1,200	1,800	3,100	4,300	4,700	5,300	NA
Flexural Strength (psi)	D790	1,700	1,700	1,700	1,700	2,700	3,000	3,000
Flexural Modulus (psi)	D790	1,500	1,700	1,700	1,700	2,700	3,000	3,000
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.008	.004-.008	.004-.006

# Tecothane® TPU Typical Physical Test Data

## CLEAR GRADES

ASTM Test	TT-1074A	TT-1085A	TT-1095A	TT-1055D	TT-1065D	TT-1069D	TT-1072D	TT-1075D-M
D2240 (Shore A Hardness)	75A	85A	94A	64B	64D	69D	74D	75D
Specific Gravity	D792	1.10	1.12	1.15	1.16	1.18	1.18	1.19
Residual Modulus (psi)	D790	1,500	2,100	3,000	3,500	25,000	45,000	50,000
Ultimate Tensile (psi)	D412	6,000	7,000	9,000	9,500	10,000	8,800	8,300
Ultimate Elongation (%)	D412	550	450	400	350	300	310	275
Tensile (psi) D412								
at 100% Elongation		500	800	1,300	2,500	2,800	3,200	3,600
at 200% Elongation		700	1,000	2,100	3,800	4,600	4,200	NA
at 300% Elongation		1,100	1,600	4,300	6,500	7,800	NA	NA
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006
Mold Shrinkage (in/in) 2100 mm (203°C)								
Mold Shrinkage (in/in) 2100 mm (203°C)								
Mold Shrinkage (in/in) 2100 mm (203°C)								

## RADIOPAQUE GRADES (20% loading of barium sulfate)

ASTM Test	TT-2074A-B20	TT-2086A-B20	TT-2095A-B20	TT-2055D-B20	TT-2065D-B20	TT-2069D-B20	TT-2072D-B20	TT-2076D-B20
D2240 (Shore A Hardness)	77A	87A	94A	64B	64D	70D	75D	77D
Specific Gravity	D792	1.30	1.32	1.35	1.36	1.38	1.38	1.40
Residual Modulus (psi)	D790	3,000	3,500	5,000	5,500	8,000	9,000	10,000
Ultimate Tensile (psi)	D412	5,200	6,600	8,200	8,600	8,700	7,500	7,600
Ultimate Elongation (%)	D412	850	800	450	360	300	320	200
Tensile (psi) D412								
at 100% Elongation		500	700	1,600	2,500	3,100	3,500	3,600
at 200% Elongation		700	1,000	2,000	3,600	4,500	4,000	NA
at 300% Elongation		1,000	1,500	3,500	6,000	7,500	6,500	NA
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006
Mold Shrinkage (in/in) 2100 mm (203°C)								
Mold Shrinkage (in/in) 2100 mm (203°C)								
Mold Shrinkage (in/in) 2100 mm (203°C)								

NOTE: TT-1069, TT-1072, TT-2069D-B20 and TT-2072D-B20 are excellent candidates for over-the-needle applications.

These test results are based on small samples of Tecothane® TPU polyurethane and do not necessarily represent average results from larger test samples. This information should not be used for establishing engineering or manufacturing guidelines.



## RADIOPAQUE GRADES (40% loading of barium sulfate)

	ASTM Test	TT-2074A-B40	TT-2085A-B40	TT-2095A-B40	TT-2055D-B40	TT-2065D-B40	TT-2075D-B40
Density (lb/in <sup>3</sup> ) (Shore Hardness)	D2240	85A	85A	87A	82D	75D	84D
Specific Gravity	D792	1.57	1.58	1.59	1.62	1.64	1.65
Flexural Modulus (ksi)	D790	2,600	3,500	3,600	2,100	58,000	43,000
Ultimate Tensile (psi)	D412	3,600	4,200	6,700	6,800	6,900	7,100
Ultimate Elongation (%)	D412	700	640	470	380	330	220
Tensile (psi)	D412						
at 100% Elongation		600	1,000	1,700	2,700	3,100	NA
at 200% Elongation		800	1,100	2,100	3,300	3,800	NA
at 300% Elongation		1,000	1,700	3,500	5,000	6,000	NA
Melt Index (g/10 min) (200°C/10.0 mm)	D1238	3.2	3.8	3.5	1.7	1.7	1.5
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.008-.010	.005-.010	.004-.008	.004-.010
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.008-.010	.004-.008	.004-.008	.004-.006

## Tecophilic® TPU Typical Physical Test Data

	ASTM Test	HP-60D-20	HP-60D-35	HP-60D-60	HP-93A-100
Durameter (Shore Hardness)	D2240	83D	82D	85D	83D
Specific Gravity	D792	1.12	1.12	1.15	1.13
Flexural Modulus (psi)	D790	4000	4000	4000	2900
Ultimate Tensile (psi)	D412				
Dry		8900	7800	8300	2200
Wet		5100	4900	3100	1400
Ultimate Elongation (%)	D412	430	450	600	640
Drop Weight Impact (ft-lb)	D352	350	300	500	620

The values reported above are based on a small sample base and should be used as approximations only.

Note: Although no physical test data is currently available for Tecogel® TPU, this hydrogel can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of the dry resin.

## Tecoplast® TPU Typical Physical Test Data

	ASTM Test	Series TP-470 Clear Resins	Series OP-770 Opaque Resins
Durameter (Shore Hardness)	D2240	82D	84D
Specific Gravity	D792	1.18	1.19
Flexural Modulus (psi)	D790	60,000	29,000
Ultimate Tensile (psi)	D638	10,000	9,000
Ultimate Elongation (%)	D638	600	250
Drop Weight Impact	D3029 (G)		
Unannealed		30 in-lb	40 in-lb
Annealed*		>40 in-lb	>40 in-lb
ASTM D528	D528	1.5	1.5
26° F (5° C) Annealed		50 F (5° C)	40 F (5° C)
284 psi (19.6 MPa)		68 F (17° C)	50 F (10° C)
Mold Shrinkage (in/in)	D955	.0014	.0014

\*Samples were annealed for 4 hours at 150°F (65°C)

The properties reported above are based on a small sample base and should be used as approximations only.

# Carbothane® TPU Typical Physical Test Data

## CLEAR GRADES

	ASTM Test	PC-3575A	PC-3585A	PC-3595A	PC-3555D	PC-3572D
Ultimate Tensile (psi)	D412	5,300	6,000	7,100	7,300	8,500
Ultimate Elongation (%)	D412	450	500	580	580	360
Tensile (psi)	D412					
at 100% Elongation		300	600	1,000	1,500	3,300
at 200% Elongation		500	900	1,900	2,300	4,100
at 300% Elongation		900	2,200	4,400	4,700	6,900
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.006

## RADIOPAQUE GRADES (20% loading of barium sulfate)

	ASTM Test	PC-3575A-B20	PC-3585A-B20	PC-3595A-B20	PC-3555D-B20	PC-3572D-B20
Ultimate Tensile (psi)	D412	6,000	6,000	8,100	8,000	7,800
Ultimate Elongation (%)	D412	330	380	450	400	310
Tensile (psi)	D412					
at 100% Elongation		400	700	1,000	1,700	3,500
at 200% Elongation		700	1,100	1,700	2,700	4,400
at 300% Elongation		1,200	2,000	3,400	4,900	6,800
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.006

These test results are based on small samples of Carbothane® TPU polyurethane and do not necessarily represent average results from larger test samples. This information should NOT be used for establishing engineering or manufacturing guidelines.

## Solution Grade Polymers

Although all Noveon polymers can be dissolved in certain solvents, certain grades have been developed specifically for use in solution casting or for coating of medical products. The solution grades differ from the extrusion grades in that they contain no melt processing lubricants.

Tecoflex® solution grade polyurethanes are available in four hardnesses; Tecophilic® solution grade polyurethanes are available in three hardnesses.

SOLUTION PROCESSIBLE GRADES	
Tecoflex	Tecophilic
SG-80A	SP-80A-150
SG-85A	SP-93A-100
SG-93A	SP-60D-60
SG-60D	

\*Note last two or three characters of the Tecophilic® TPU product represent the approximate equilibrium water content.

Solution processing guidelines can be found in Noveon's Processing Information Booklet

Noveon disclaims any warranty of its products (Tecoflex®, Tecothane®, Carbothane®, Tecoplast®, Tecophilic® and Tecogel®) for merchantability or fitness for any particular application. Any person who intends to use these resins in the manufacture of implantable or any other medical device must independently determine the suitability of these resins for such applications. Each person is responsible for obtaining all necessary FDA and other approvals for the use of these resins in such an application and for complying with all applicable laws relating to the manufacture and sale of medical devices.



## Tecoflex<sup>®</sup> 1-MP Adhesive

Medical Grade Tecoflex<sup>®</sup> 1-MP is a one-part adhesive based on a fast-crystallizing polyurethane resin. The adhesive has been used with good results on the following substrates: polyurethanes, plasticized vinyls, polycarbonates, acrylics, chlorinated SBR rubbers, and primed metals.

### Specifications:

**Material:** The adhesive is a solution of a polyurethane based polymer in methyl ethyl ketone and methylene chloride.

**Solids:** 8% by weight 1%.

**Viscosity:** When tested with a Brookfield Viscometer, Model RVF, Spindle #2, at 50 RPM, the viscosity at 70°F is 200-900 cps.

**Color:** The adhesive has a light gray, translucent appearance.

### Directions For Use:

The adhesive can be used in two ways: either as a pressure sensitive bonding agent, or as a delayed-action adhesive, where coated parts can be stacked and subsequently reactivated by either infrared heating or solvent wipe. Both surfaces to be adhered should be cleaned thoroughly with alcohol and allowed to dry. 1-MP adhesive is applied to both surfaces with a brush, roller or other applicator and air dried. This procedure should be repeated until 3 coats of adhesive have been applied to both surfaces. The adhesive may be activated using an infrared source. Upon activation, the two surfaces are plied together under light pressure until adequate bonding has developed (usually about one minute). Total adhesive strength is achieved in about 24 hours. Alternatively, the adhesive may be activated by wiping the two surfaces with a small amount of methyl ethyl ketone. The surfaces are then plied together as described above.

### Precautions:

The adhesive should be used in a well-ventilated area to minimize worker exposure to vapors. The adhesive will retain potency for at least 18 months if sealed in original container and not exposed to ultraviolet light. Some settling may occur during storage. This will not decrease the adhesion capability. It is recommended that the adhesive be shaken or stirred for 2 minutes prior to use. Since the adhesive is a thixotropic solution, its viscosity will be lowered upon application of shear forces. To lower viscosity, the adhesive should be diluted using a mixture of methylene chloride and methyl ethyl ketone in a 60:40 ratio by weight. In high humidity, water droplets may condense on the drying film due to the cooling effect of evaporating solvent. Water interferes with bonding. This condition can be avoided by controlling ambient humidity.

**NOTE:** Due to the flammability of this product, special packaging is required for overseas air shipments.

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**1-MP Adhesive Strength of EG-60D to Other Materials:****MINIMUM ADHESIVE STRENGTH (PLI)**

EG-60D to EG-60D	15.0
Rigid PVC to EG-60D	16.0
Pellethane 65D to EG-60D	12.0
Acrylic to EG-60D	15.0
Polycarbonate to EG-60D	14.0
Primed 316 Stainless to EG-60D	14.5
Primed Ti-6Al-4V to EG-60D	14.5

Values are intended as an engineering guideline. The potential user must perform any and all pertinent tests in order to determine the suitability of the material for the intended application. It is the responsibility of the user to obtain any and all governmental approvals in order to comply with applicable regulatory requirements governing the use of the material in a medical or food handling device application. The final determination of fitness of the material for any specific application is the responsibility of the buyer.

Specimens were prepared by applying three coats of adhesive to clean specimens followed by air dry for six hours. Specimens were heat activated with IR lamps, plied together under 1000 psi pressure for one minute, and cured for 24 hours at 24°C.

Adhesive bond strength was measured at 90° in tension with a cross-head speed of 20 IPM. Results given are the average of three tests.

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# Tecoflex<sup>®</sup> TPU MG

## Physical Test Data

A series of high durometer, medical grade aliphatic, polyether-based polyurethanes with the physical properties of engineering plastics.

ASTM TEST	MG-8020	MG-8020-B20	MG-8812	MG-8812-B20
Durometer (shore hardness)	D2240 79D	75D	83D	78D
Appearance	Clear	Radiopaque	Clear	Radiopaque
Specific Gravity	D792 1.11	1.13	1.12	1.11
Flexural Modulus (psi)	D790 165,000	185,000	230,000	270,000
Ultimate Tensile (psi)	D412 4,700	7,580	8,900	8,200
Ultimate Elongation (%)	D412 60	45	6	9
Tensile (psi)	D412			
at 100% Elongation		N/A	N/A	N/A
at 200% Elongation		N/A	N/A	N/A
at 300% Elongation		N/A	N/A	N/A
Melt Index (gm/10 min at 2160 gm load)	D1238 5.5 (190°C)	10.5 (190°C)	2.2 (190°C)	6.5 (190°C)
Moisture Absorption (g/in)	D955 0.13	0.11	0.15	0.14

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## **Tecogel<sup>®</sup> TPU**

Tecogel<sup>®</sup> TPU is a member of our hydrophilic family of products. Tecogel<sup>®</sup> is an aliphatic polyether-based polyurethane that can absorb between 5 times (TG-500) to 20 times (TG-2000) its weight in water.

Tecogel<sup>®</sup> TG-2000 TPU is a cohesive gel in water whereas Tecogel<sup>®</sup> TG-500 TPU is a flexible solid when fully hydrated. Both materials are soluble/dispersible in ethanol/water mixes. The ethanol water ratios that can be used range from 50% ethanol to 90% ethanol. Other solvents such as THF/water, and DMAC (above 40°C) are also good solvents for Tecogel<sup>®</sup> TPUs. These materials may be suitable as a reservoir for drugs in drug delivery systems.

Special modifiers (such as UV stabilizers) can be added (please consult Noveon's sales office at 888-234-2436 for further details).

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Committed to  
providing medical  
grade thermoplastic  
polyurethane resins.

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# Noveon's Family of TPUs

Noveon continues to supply the medical device industry with an outstanding array of thermoplastic polyurethanes (TPUs). Each of our family of TPU products – Tecoflex®, Tecothane®, Carbothane®, Tecoplast® and Tecophilic® has been specifically formulated to have good biocompatibility, flexural endurance, high strength and processing versatility over a wide range of applications. Noveon's families of TPUs are now being used in many medical devices with new applications continually being found by device manufacturers who encounter demanding tissue or blood contact situations.

# Meeting the Challenge

Body tissue and blood present difficult environments for elastomeric components of indwelling medical devices. Such components must be able to withstand extended exposure to hostile aqueous environments at body temperature and the corrosive biochemical composition of blood and body fluids that can degrade many materials. At the same time, the device must cause as few complications to the patient as possible. Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an indwelling medical device. Furthermore, the elastomeric component must be strong and easy to manufacture into small, precise shapes and sizes specified by device designers. For example, it is important to keep catheters as small as possible when they are entering the circulatory system – a common application for cardiovascular diagnostic and clinical devices.

Resins with biocompatibility and biostability are critical components in medical device manufacturing. Noveon offers a wide variety of thermoplastic polyurethanes that are designated as medical grade biomaterials having passed either USP Class VI, MEM Elution or other relevant tests in order to establish their biocompatibility and biostability.



# The Materials of Choice



Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an implanted medical device.

Noveon's polyurethanes are reaction products synthesized from diisocyanates, macrodiols and chain extenders. The characteristics of each polyurethane can be attributed to its structure. Polyurethanes are made of hard and soft domains where the diisocyanate and extender make up the hard domains and the macrodiol makes up the soft domain. Varying the ratios of these two domains allows polyurethanes to be formulated with durometers as soft as 72A or as hard as 84D (Shore Hardness).

Polyurethanes are designated aromatic or aliphatic on the basis of the chemical nature of the diisocyanate component in their formulation. Tecoflex®, Tecophilic® and Carbothane® resins are manufactured using the aliphatic compound, hydrogenated methylene diisocyanate (HMDI). Tecothane® and Tecoplast® resins use the aromatic compound methylene diisocyanate (MDI). All the formulations, with the exception of Carbothane® resins are formulated using polytetramethylene ether glycol (PTMEG) and 1, 4 butanediol chain extender. Carbothane® resins are specifically formulated with a polycarbonate diol (PCDO). These represent the major chemical composition differences among the various families.

Aromatic and aliphatic polyurethanes share similar properties that make them outstanding materials for use in medical devices. In general, there is not much difference between medical grade aliphatic and aromatic polyurethanes with regard to the following chemical, mechanical and biological properties:

- High tensile strength (4,000 – 10,000 psi)
- High ultimate elongation (250 – 700%)
- Wide range of durometer (72 Shore A to 84 Shore D)
- Good biocompatibility
- High abrasion resistance
- Good hydrolytic stability
- Can be sterilized with ethylene oxide and gamma irradiation
- Retention of elastomeric properties at low temperature
- Good melt processing characteristics for extrusion, injection molding, etc.

With such an impressive array of desirable features, it is no wonder that both aliphatic and aromatic polyurethanes have become increasingly the material of choice in the design of medical grade components. There are, however, distinct differences between these two families of polyurethane that could dictate the selection of one over the other for a particular application:

## Yellowing

In their natural states, both aromatic and aliphatic polyurethanes are clear to very light yellow in color. Aromatics, however, can turn dark yellow to amber as a result of melt processing or sterilization, or even with age. Although the primary objection to the discoloration of aromatic clear tubing or injection molded parts is aesthetic, the yellowing, which is caused by the formation of a chromophore in the MDI portion of the polymer, does not appear to affect other physical properties of the material.

Radiopaque grades of Tecothane® resins also exhibit some discoloration during melt processing or sterilization. However, both standard and custom compounded radiopaque grades of Tecothane® resins have been specifically formulated to minimize this discoloration.

## Solvent Resistance

Aromatic polyurethanes exhibit better resistance to organic solvents and oils than do aliphatics – especially as compared with low durometer (80 – 85 Shore A) aliphatics, where prolonged contact can lead to swelling of the polymer and short-term contact can lead to surface tackiness. While these effects become less noticeable at higher durometers, aromatics exhibit little or no sensitivity upon exposure to the common organic solvents used in the health care industry.

## Softening at Body Temperature

Both aliphatic and aromatic polyether-based polyurethanes soften considerably within minutes of insertion in the body. Many device manufacturers promote this feature of their urethane products because of patient comfort advantage as well as the reduced risk of vascular trauma. However, this softening effect is less pronounced with aromatic resins than with aliphatic resins.

## Carcinogenic By-Products

If aromatic polyurethanes are improperly processed, such as when tubing is extruded from resin with too high a moisture content or the finished components are steam sterilized, it is possible to experience the formation of measurable amounts of methylene dianiline (MDA). MDA is listed as a carcinogen. It is not possible to form MDA with an aliphatic polyurethane. Moreover, the analogous diamine which could be formed from HMDI is not listed as a carcinogen.

## Melt Processing Temperatures

Tecothane®, Tecoplast® and Carbothane® resins melt at temperatures considerably higher than Tecoflex® and Tecophilic® resins. Therefore, processing by either extrusion or injection molding puts more heat history into products manufactured from Tecothane®, Tecoplast® and Carbothane® resins. For example, Tecoflex® EG-80A and EG-60D resins mold at nozzle temperatures of approximately 310°F and 340°F respectively. Tecothane® and Carbothane® TPU products of equivalent durometers mold at nozzle temperatures in the range of 380°F to 435°F.



Noveon strives for lot-to-lot consistency to ensure ease of processing by our customers.

# The TPU Product Family

Each of our families of resins has unique characteristics that must be considered when selecting a material for your application. The following summaries will guide you in the selection of the proper material for your specific needs.

## Tecoflex® TPU

A family of aliphatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. These resins are easy to process and do not yellow upon aging. Solution grade versions are candidates to replace latex. Caution must be observed in evaluating these resins, especially the low durometer grades, in long-term implant applications because of the potential for stress cracking.

## Tecothane® TPU

A family of aromatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane® resins to exhibit improved solvent resistance and biostability when compared with Tecoflex® resins of equal durometers. As with any aromatic polyurethane, Tecothane® resins tend to yellow upon aging or when subjected to radiation sterilization.

## Carbothane® TPU

A family of aliphatic, polycarbonate-based TPUs available over a wide range of durometers, colors, and radiopacifiers. This type of TPU has been reported to exhibit excellent oxidative stability, a property which may equate to excellent long-term biostability. This family, like Tecoflex® TPUs, are easy to process and do not yellow upon aging.

## Tecophilic® TPU

A family of aliphatic, polyether-based TPUs which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating applications. Tecogel® TPU, a new member to the Tecophilic® TPU family, is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin. The materials were designed as a coating cast from an ethanol/water solvent system. Other solvent systems such as THF/water and DMAC can be used. Tecogel® TPU is melt processible using modified injection molding and extrusion methods.

## Tecoplast® TPU

A family of aromatic, polyether-based TPUs formulated to produce rugged injection molded components exhibiting high durometers and heat deflection temperatures. Tecoplast® TPU is intended for use as hubs and fittings manufactured as individual components or insert molded onto tubing. Available as clear as well as transparent and opaque colors.



Our 30,000 square foot warehouse allows us to ship standard products from stock typically within 24 hours of receipt of your order.

# Selection Guide

	TECOFLEX® TPU (polyether-based)	TECOTHANE® TPU (polyether-based)	CARBOTHANE® TPU (polycarbonate-based)	TECOPHILIC® TPU (polyether-based)	TECOPLAST® TPU (polyether-based)
Aliphatic or Aromatic	Aliphatic	Aromatic	Aliphatic	Aliphatic	Aromatic
Durometer Range	72A-83D	75A-77D	73A-75D	83A-72D	82D-84D
Regulators Sulfur Bismuth Salts Thiols	Barium Sulfate Bismuth Salts Thiols	Barium Sulfate Thiols	Barium Sulfate Thiols	Barium Sulfate Bismuth Salts Thiols	N/A
Custom Colors	Yes	Yes	Yes	Limited	Yes
Solution Grades	Yes	No	No	Yes	No
Extrusion and/or Injection Molding	Both	Both	Both	Both	Injection Molding (Primarily)
Melt Processing Temperature Range	150-190	200-220	180-220	125-180	210-230
Relative Degree of Biostability	Good	Better	Best	Not Determined	Not Determined

\*Tecothane®, Carbothane® and Tecoplast® TPUs can be dissolved in organic solvents but Tecoflex® and Tecophilic® TPUs have grades that have been designed to dissolve more readily in these type solvents.

## Radiopaque and Color Compounding

Noveon's polyurethanes can be loaded with radiopaque materials for detection by X-ray or fluoroscopy and colored for product identification or coding. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixtures and superior smoothness of the final polymer. All additives are thoroughly screened and carefully tested for chemical stability, biocompatibility and performance in the resin before use as a radiopaque or coloring agent.

Our natural grades of each family are clear (transparent) in color. The polyurethane can be made radiopaque by adding barium sulfate. Tungsten powder has also been used as an effective radiopacifier with many of our grades of resin. Bismuth subcarbonate has been used very successfully in conjunction with the Tecoflex® TPU family of products. Noveon has many stock grades containing 20% and 40% barium sulfate and can custom formulate higher loadings upon request.

Transparent colors of our products can be produced using reactive dyes that chemically combine into the urethane chain, creating an unleachable covalent bond for color permanence and non-cytotoxicity. Opaque colors are formed with high-density pigment powders that are thoroughly dispersed for color uniformity and smooth consistency. Opaque colors may be chosen using a color matching chart or by matching existing components.

## Custom Tubing Extrusion

Noveon operates a complete tubing production facility specially designed to extrude our various polyurethane products. All Noveon tubing passes strict quality control criteria at each stage of production and conforms to specifications of Good Manufacturing Practices. All tubing at Noveon is produced by custom order to ensure exact dimensions and configuration.

Noveon's families of polyurethanes have excellent working characteristics that allow extremely small diameters and very complex lumen configurations to be extruded. Specialty operations, such as radiopaque stripe coextrusion, are done on a regular basis. Tubing requiring specific radiopaque loadings or exact color matching is also done on a regular basis allowing manufacturers to order tubing that meets their desired specifications. Noveon's expert extrusion engineers have developed capabilities to extrude tubing with lumen diameters as small as .005 inch and lumen quantities up to 9 lumens. Orders of 3 to 6 lumens are not uncommon. Noveon's technical staff works with clients to assure all tubing meets the tolerances and characteristics necessary to ensure top performance in its function within the medical device.

Noveon, Inc. disclaims any warranty of its products (Tecoflex®, Tecothane®, Carbothane®, Tecoplast®, Tecophilic® and Tecogel®) for merchantability or fitness for any particular application. Any person who intends to use these resins in the manufacture of implantable or any other medical device must independently determine the suitability of these resins for such applications. Each person is responsible for obtaining all necessary FDA and other approvals for the use of these resins in such an application and for complying with all applicable laws relating to the manufacture and sale of medical devices.



# Our Commitment

The quality of Noveon's family of polyurethane products reflects the expertise of the Noveon staff. This group of knowledgeable professionals stands ready to assist our customers in applying our products to both existing and next-generation requirements.

Close interaction with customers provides us with feedback essential for improving our own products. At the same time, it helps to determine improved methods that can maximize the quality and cost effectiveness of our customers' end products. Our staff is well versed in materials handling, processing methods and product design.

In a time when other manufacturers are retreating from the medical market, Noveon reaffirms its commitment to continue supplying medical grade thermoplastic polyurethane resins.

Detailed product pamphlets are available to identify the unique characteristics of each of our families of polyurethane. For more information about our products or services call: 888-234-2436. Visit our web site at [www.estane.com](http://www.estane.com).

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